REMARKS

I. Status of the Application

Applicants note that any amendments or cancellation of claims are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),[1] and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

Claims 1-17 were originally filed in the present application

Applicants herein cancel claims 6 and 8-17, while reserving the right to prosecute these or similar claims in the future. Applicants herein amend claims 1 and 7. Support for amendments to claim 1 can be found throughout the application, for example, at page 18, line 13 through page 20, line 30. Applicants also herein add new claims 18-21. Support for these claims can be found throughout the application, for example, at page 8, lines 1-6, and at page 18, line 13 through page 20, line 30.

Claim 7, as well as the specification, have been amended in order to avoid the use of trademarks. As such, trademarks have been capitalized and chemical names have been provided for certain trademarked compounds as requested in the Office Action mailed January 3, 2006. As such, no new matter has been added.

Accordingly, Claims 1-5, 7 and 18-21 are pending in the application.

II. The Claims Are Enabled

The Examiner rejected Claims 8-15 under 35 U.S.C. §112 as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. Applicants respectfully disagree.

Nonetheless, Applicants have canceled (while reserving the right to prosecute these or similar claims in the future) claims 8-17, rendering this rejection moot.

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[1] 65 Fed. Reg. 54603 (Sept., 8, 2000).

III. The Claims Are Not Anticipated

A) Rodgers et al. (U.S. Pat. No. 6,821,953) Does Not Anticipate the Claims

The Examiner rejected Claims 1-17 under 35 U.S.C. §102(b) as allegedly being anticipated by Rodgers et al., (U.S. Pat. No. 6,821,953, hereinafter "the '953 patent"). Applicants respectfully disagree.

The '953 patent does not provide a method of treating a subject comprising providing a subject with inflammatory bowel disease or short bowel syndrome and a therapeutic composition comprising an angiotensin converting enzyme inhibitor, and administering the composition to the subject under conditions such that the severity of inflammatory bowel disease or short bowel syndrome is reduced in said subject. Instead, the '953 patent provides a method of treating and preventing damage to mucosal tissue comprising administering to a subject an active agent comprising a peptide fragment of 3-8 amino acids. The '953 patent also suggests that the method of treating and preventing damage to mucosal tissue (i.e., with an active agent comprising a peptide fragment of 3-8 amino acids) may also comprise treating with another compound for treating or preventing damage to mucosal tissue, wherein the other compound is selected from the group consisting of anti-inflammatory drugs, angiotensin converting enzyme (ACE) inhibitors, anti-infectives, growth factors, and antihistamines.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."[2] Furthermore, the law requires that the single prior art reference provide an *enabling* disclosure of the claimed invention.[3] Importantly, a prior art reference provides an enabling disclosure only "if the public was in possession of the claimed invention before the date of invention."[4]

The Examiner alleges that the '953 patent teaches the administration of angiotensin converting enzyme (ACE) inhibitors in various inflammatory conditions of the bowel and that ulcerative colitis is one example of an inflammatory bowel disease (Column 9, line 62).

However, the '953 patent, in order to anticipate, must do more than simply mention all of the components of the claimed invention. Under the law, an anticipatory reference must teach

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[2] *Verdegaal Bros. v Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987), and MPEP 2131.
[3] See, e.g., MPEP 2121.01.
[4] See, e.g., MPEP 2121.01.

these components *as arranged in the claims*.[5] The Examiner has failed to allege that the '953 patent teaches the claimed components as arranged in the claims, but instead simply asserts that the '953 patent mentions all of the components - this is not enough under the law.

In order to overcome this deficiency, the Examiner has picked various components from a disparate laundry list of examples of diseases and/or injury conditions that may benefit from the method of treating and preventing damage to mucosal tissue with an active agent comprising a peptide fragment of 3-8 amino acids of the '953 patent.[6] The rejection does not cite to language within the '953 patent that would allow the skilled artisan background sufficient to practice the instant invention without undue experimentation.

This is not surprising as the '953 patent does not provide any type of administration protocol for how an angiotensin converting enzyme inhibitor could be used to treat an inflammatory bowel disease (e.g., ulcerative colitis) nor does the '953 patent provide any examples (*in vitro* or *in vivo*) demonstrating the use of an angiotensin converting enzyme inhibitor in the treatment of inflammatory bowel disease or short bowel syndrome. Thus, the '953 patent fails to provide guidance to one of skill in the art regarding how to use an angiotensin converting enzyme inhibitor for treating an inflammatory bowel disease.

Accordingly, there exists no clear direction or guidance provided by the '953 patent enabling the use of angiotensin converting enzyme inhibitors for the treatment of inflammatory bowel disease or short bowel syndrome. Applicants respectfully request that this rejection be withdrawn.

B) Acton et al. (U.S. Pat. No. 6,632,830) Does Not Anticipate the Claims

The Examiner rejected Claims 1-17 under 35 U.S.C. §102(b) as allegedly being anticipated by Acton et al., (U.S. Pat. No. 6,632,830, hereinafter "the '830 patent"). Applicants respectfully disagree.

The '830 patent does not provide a method of treating a subject comprising providing a subject with inflammatory bowel disease or short bowel syndrome and a therapeutic composition comprising an angiotensin converting enzyme inhibitor, and administering the composition to the subject under conditions such that the severity of inflammatory bowel disease or short bowel

[5] *See, In re King,* 231 USPQ 136, 138 (Fed. Cir. 1986), and MPEP 2131.
[6] U.S. Pat. No. 6,821,953, Column 9, lines 47-63.

syndrome is reduced in said subject. Instead, the '830 patent provides angiotensin converting enzyme (ACE) 2 inhibitors. Specifically, the '830 patent teaches the synthesis of various ACE-2 inhibitor compounds (See, e.g., Column 43, line 60 through Column 167, line 6).

The Examiner alleges that the '830 patent teaches the administration of an angiotensin converting enzyme (ACE) inhibitor in the treatment of an inflammatory bowel disease (Column 36, lines 17-34 and 60-61). However, as described above, the '830 patent, in order to anticipate, must do more than simply mention all of the components of the claimed invention. Under the law, an anticipatory reference must teach these components *as arranged in the claims.*[7] The rejection does not allege that the '830 patent teaches the claimed components as arranged in the claims, but instead simply asserts that the '830 patent mentions all of the components - this is not enough under the law.

In order to overcome this deficiency, the Examiner has picked various components from a disparate laundry list of examples of ACE-2 associated states that might benefit from administration of an ACE-2 inhibiting compound of the '830 patent.[8] What the rejection fails to do is cite to language within the '830 patent that would allow the skilled artisan background sufficient to practice the instant invention without undue experimentation.

This is not surprising as the '830 patent does not provide any particular examples of inflammatory bowel diseases that might benefit from administration of an ACE-2 inhibiting compound or any specific administration protocol for how an ACE-2 inhibitor could be used to treat an inflammatory bowel disease (e.g., ulcerative colitis). The '830 patent further fails to provide any examples (*in vitro* or *in vivo*) demonstrating the use of an ACE-2 inhibitor in the treatment of inflammatory bowel disease or short bowel syndrome. Thus, the '830 patent fails to provide guidance to one of skill in the art regarding how to use an angiotensin converting enzyme inhibitor for treating an inflammatory bowel disease.

Accordingly, there exists no clear direction or guidance provided by the '830 patent enabling the use of angiotensin converting enzyme inhibitors for the treatment of inflammatory bowel disease or short bowel syndrome. Applicants respectfully request that this rejection be withdrawn.

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[7] *See, In re King,* 231 USPQ 136, 138 (Fed. Cir. 1986), and MPEP 2131.
[8] U.S. Pat. No. 6,632,830, Column 36, lines 35-67.

III. The Claims are Not Obvious

The Examiner rejected Claims 1-15 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Studdy et al., Lancet (abstract) in view of Rao et al., Indian Journal of Pharmacology (abstract). Applicants respectfully disagree.

A *prima facie* case of obviousness requires the Examiner to provide a reference(s) which (a) discloses all of the elements of the claimed invention, (b) suggests or motivates one skilled in the art to combine the claimed elements to produce the claimed combination, and (c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of these three requirements precludes a finding of a *prima facie* case of obviousness and without more entitles the Applicants to allowance of the claims in issue.[9]

Applicants respectfully submit that the cited references, individually or combined, do not teach each element of the present invention.

Specifically, neither Studdy et al. nor Rao et al., individually or in combination, teach or disclose a method of treating a subject comprising providing a subject with inflammatory bowel disease or short bowel syndrome and a therapeutic composition comprising an angiotensin converting enzyme inhibitor, and administering the composition to the subject under conditions such that the severity of inflammatory bowel disease or short bowel syndrome is reduced in said subject.

Accordingly, applicants respectfully request that rejection of Claim 1, and claims dependent thereon, under 35 U.S.C. § 103(a) be withdrawn.

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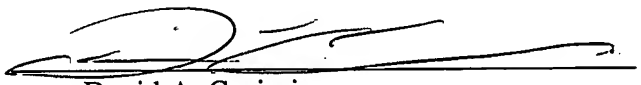
[9] *See, e.g., Northern Telecom Inc. v. Datapoint Corp.*, 15 USPQ2d 1321, 1323 (Fed. Cir. 1990).

CONCLUSION

For the reasons set forth above, it is respectfully submitted that Applicants have addressed all grounds for rejection and Applicants' claims should be passed to allowance. Reconsideration of the application is respectfully requested. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: May 3, 2006



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